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DETAILED ACTION

Claims 1-18 are pending in the instant application.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Claims 1-18 are drawn to more than one inventive concept (as defined in PCT Rule 13), and accordingly, a restriction is required according to the provision of PCT Rule 13.2

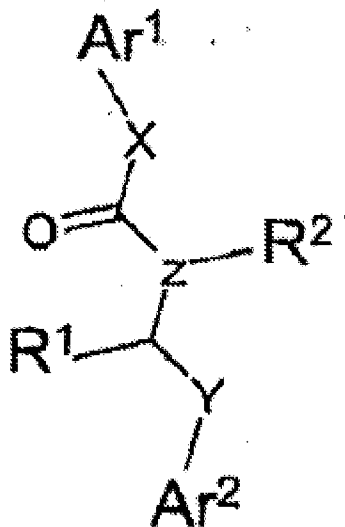
PCT Rule 13.2 states that the international application shall relate to one invention only or to a group of inventions so linked as to form a general inventive concept (requirement of unity of invention).

PCT Rule 13.2 states that unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features *that makes a contribution over the prior art*.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

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Group I: Claims 1-11 and 13-18 drawn to a compound of formula (I),



, classified in various subclasses of classes 540, 544, 546, 548 and 549. If this group is elected, applicants are requested to elect a single species for search purposes. For example, a compound of formula (I), wherein X is NH; Ar1 is phenyl, Z is CH; R2 is H; R1 is H; Y is CH2 and Ar2 is phenyl.

Group II: Claim 13 drawn to a method of using a compound of formula (I), classified in various subclasses of classes 514, 540, 544, 546, 548 and 549. If this group is elected, applicants are requested to elect a single species for search purposes. For example, a compound of formula (I), wherein X is NH; Ar1 is phenyl, Z is CH; R2 is H; R1 is H; Y is CH2 and Ar2 is phenyl.

In the instant case, upon election of a single compound, the Office will review the claims and disclosure to determine the scope of the independent invention encompassing the elected compound (compounds which are so similar thereto as to be within the same inventive concept and reduction to practice). The scope of an independent invention will encompass all compounds within the scope of the claim,

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which fall into the same class and subclass as the elected compound, but may also include additional compounds, which fall in related subclasses. Examination will then proceed on the elected compound AND the entire scope of the invention encompassing the elected compound as defined by common classification. A clear statement of the examined invention, defined by those class(es) and subclass(es) will be set forth in the first action on the merits. Note that the restriction requirement will not be made final until such time as applicant is informed of the full scope of compounds along with (if appropriate) the process of using or making said compound under examination.

The claims herein lack unity of invention under PCT rule 13.1 and 13.2 since, under 37 CFR 1.475(a) the compounds defined in the claims lack a significant structural element qualifying as the special technical feature that defines a contribution over the prior art.

Accordingly, unity of invention is considered to be lacking and restriction of the invention in accordance with the rules of unity of invention is considered to be proper. Additionally, the vastness of the claimed subject matter, and the complications in understanding the claimed subject matter imposes a serious burden on any examination of the claimed subject matter.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

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The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

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Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

In addition, because of the plethora of classes and subclasses in each of the Inventions, a serious burden is imposed on the examiner to perform a complete search of the defined areas. Therefore, because of the reasons given above, the restriction set forth is proper and not to restrict would impose a serious burden in the examination of this application.

Advisory of Rejoinder

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The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Telephonic Election

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During a telephone conversation with Attorney Mark Wieczorek on 1/13/11 and 1/18/11 a provisional election was made *without traverse* to prosecute the invention of Group I, comprising Claims 1-11 and 13-18 of Formula I depicted in claim 1. The election of species of the compound of ID1 in Table 1 found on page 48 of the instant specification is also acknowledged, wherein X is NH; Ar1 is 3,4-dichlorophenyl; Z is CH; R2 is CH₂-COOH; R1 is H; Y is a valence bond; Ar2 is *p*-Cl-phenyl. Affirmation of this election must be made by applicant in replying to this Office action.

Priority

This application is a 371 of PCT/EP04/06260, filed 06/10/2004.

Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d) by application no. EPO03090177 filed in the European Patent Office on 06/10/2003, which papers have been placed of record in the file. The application names an inventor or inventors named in the prior application.

Elected species

The elected species, found in Table 1, compound ID1, is found free of the prior art and is allowable at this point in examination. The scope of the invention has been expanded.

Scope of the Elected Invention

Claims 1-18 are pending in this application. Claims 4-5, 12, and 14-17 are withdrawn from further consideration by the examiner, 37 C.F.R. §1.142(b), as being drawn to a non-elected invention. The withdrawn subject matter is patentably distinct from the elected subject matter as it differs in structure and element and would require

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separate search considerations. In addition, a reference, which anticipates one group, would not render obvious the other.

The scope of the elected subject matter that will be examined and searched is as follows: Claims 1-3, 6-11, 13 and 18, drawn to a compound of formula (I), wherein

X is NH;

Ar1 is phenyl optionally substituted;

Z is CH;

R2 is Q-CO₂H, wherein Q is a bond or CH₂;

R1 is hydrogen or methyl;

Y is a valence bond; and

Ar2 is phenyl optionally substituted.

Claim Rejections - 35 USC § 112, 2nd paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 8-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims must stand alone to define the invention and incorporation into claims by express reference to the specification is not permitted. Ex parte Fressola, 27 USPQ 2d 1608. Claims that require one to read the specification to determine the metes and bounds of the invention are repugnant to modern practice in the Office and are properly rejected under 35 USC 112, 2nd

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paragraph, as failing to particularly point out and distinctly claim the invention. Id. At 1609.

Claim 1 is indefinite because the metes and bounds of R1 and R2 cannot be ascertained. It appears from claim 1 that R1 is hydrogen or methyl only, but in claim 6, for example, R1 is Q-CO₂H, Q-1H-tetrazo-5-yl, Q-CN, etc... Applicants must clarify the R1 and R2 variable in claim 1.

Claim 1 is rejected for the terms “wherein R5 is a functional group that is hydrolyzed to –CO₂H in physiological conditions,” “wherein one or two non-adjacent methylene units of Q are optionally and independently replaced by,” “an ensemble of two 3-8 membered monocyclic rings covalently linked by,” and “bivalent spacer group.” The metes and bounds of these terms cannot be ascertained. It is unclear what moieties these terms are referring and the compound cannot at once be envisioned based on these vague terms. It is suggested that the terms be deleted as superfluous or replaced with more art recognized terms.

Claims 8 and 11 are improperly dependent from Claims 1 and 9 for failure to limit the scope of Claims 1 and 9. Claims 8 and 11 are drawn to compounds or compositions of Claims 1 and 9 and further recite the intended use of the compounds. However, intended use is not a limitation of a compound. *In re Hack*, 114 PQ 161 (CCPA 1957). Therefore, Claims 8 and 11 are improper and substantial duplicates of the claims from which they depend. By deleting Claims 8 and 11, the rejection would be overcome.

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Claim 9 is rejected as indefinite because it is drawn to a pharmaceutical composition however the only component to the composition a compound of claim 1, which makes claim 9 a substantial duplicate of claim 1. Composition claims require at least two elements. Also the compound of claim 1 is unclear. It is suggested that the term "formula (I)" be inserted after the term compound to clarify it is the same compound. A more definite composition claim would read as follows: a pharmaceutical composition comprising a compound of formula (I) of claim 1 and a pharmaceutically acceptable carrier.

Claim 10 is rejected as indefinite because it is drawn to a pharmaceutical composition however the terms "compound" and "mixed" are unclear. Claim terms are indefinite when the metes and bounds of the term cannot be determined. It is suggested that the term "and" replace the term "mixed" and that formula (I) be inserted after the compound. This would clarify that a pharmaceutically acceptable carrier is always present with the compound of formula (I).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 6-8, 13 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Joshi et al, J. of Univ. of Bombay, 1962, Vol. 30(50-51), pp.5-9.

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Applicants claims relate to compound of Formula (I) in claim 1. Joshi discloses compounds that anticipate the instantly claimed genus wherein: X is NH; Z is CH; Y is a bond; R1 is methyl; R2 is COOH; and Ar1/2 are optionally substituted phenyl.

See CAS RN 93880-22-9, α -methyl- β -((4-nitrophenyl)amino)carbonyl)-benzenebutanoic acid; CASN RN 94165-19-2, α -methyl- β -((phenylamino)carbonyl)-benzenebutanoic acid; CAS RN 95157-51-0, α -methyl- β -((4-chlorophenyl)amino)carbonyl)-benzenebutanoic acid; CAS RN 95317-81-2, α -methyl- β -((4-methoxyphenyl)amino)carbonyl)-benzenebutanoic acid.

Specification

The title of the invention "Use of a compound of formula 1 for making a pharmaceutical composition" is not descriptive. The reason the title is not descriptive is because it is unclear what the compound of formula 1 is. A new title is required that is clearly indicative of the invention to which the claims are directed.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susannah Chung whose telephone number is (571) 272-6098. The examiner can normally be reached on M-F, 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Susannah Chung/
Examiner, Art Unit 1626